JUL 1 - 2005

510(k) Summary
Navigator Patient Head/Neck Positioning and Position Monitoring System

K042875

1. Submitter Information

Contact: Leigh Spotten
Director of Quality and Regulatory Affairs
North American Scientific, Inc.
20200 Sunburst Street
Chatsworth, CA 91311
Email: Leigh.Spotten@nasmedical.com
Phone: (818) 734-8600 Ext. 209

2. General Provisions

Common/Usual Name: Patient Positioning and Monitoring System

Proprietary Name: Navigator Patient Positioning and Monitoring System

Classification: Class II

3. Predicate Devices

The system addressed in this submission is substantially equivalent to the following predicate devices:

Device	Clearance Number	Clearance Date
(1) RadioCameras™ Localization and Positioning System	K000246	1/7/2000
(2) RadioCameras™ System Head/Neck Application	K994355	3/22/2000
(3) BAT™ Ultrasound Localization and Positioning System	K981424	7/17/1998

This substantial equivalence was established by comparison of functions and features and the use of an essentially identical optical position location device from the same commercial manufacturer.

4. Intended Use

This submission describes a system intended for use with a linear accelerator in Radiation Therapy(RT)/stereotactic Radiosurgery(RS) to position a patient relative to the isocenter of the linear accelerator and to monitor the patient's location relative to that position.

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5. System Description

The Navigator System utilizes a high resolution optical tracking system to determine and monitor the position of optical markers attached to the patient as the means to locate and monitor the position and orientation of the patient, relative to treatment isocenter.

The Navigator System consists of the following major components:

a. A high resolution optical camera array and illuminator.
b. A computer workstation.
c. An optical positioning device.
d. An optical calibration device.

6. Performance Standards

Performance standards for this type of system have not been established by the FDA under Section 514 of the Food, Drug, and Cosmetic act.

7. Biocompatibility

The materials used in system components that contact the patient are USP classified for skin contact or 510(k) cleared. These materials have a long history of safe use in dental applications. Their use in this system does not raise any new issues related to safety and effectiveness.

8. Summary of Substantial Equivalence

This system is similar in design, construction, materials, intended use, and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 - 2005

Mr. Leigh Spotten
Director of Quality and Regulatory Affairs
NOMOS Corporation
200 W. Kensinger Dr., Suite 100
CRANBERRY TOWNSHIP PA 16066

Re: K042875
Trade/Device Name: nTrak Patient Position and Monitoring System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, MUJ
Dated: June 9, 2005
Received: June 10, 2005

Dear Mr. Spotten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042875

Device Name: nTRAK Patient Positioning and Monitoring System

Indications for Use:

The nTRAK Patient Positioning and Monitoring System is Intended for use with a linear accelerator in Radiation Therapy(RT)/ stereotactic Radiosurgery(RS) to position a patient relative to the isocenter of the linear accelerator and to monitor the patient's location relative to that position.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042875